Original article

Effect of turbinoplasty in concha bullosa induced rhinogenic headache, a randomized clinical trial

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Background: Rhinogenic origin is an important source for headache, which may be treated by medical or endoscopic intervention. An aim of this study was to clarify whether the surgical or medical intervention is superior. **Materials and Methods:** In this randomized double blind clinical trial study, 44 patients (19 male and 25 female) with periorbital or frontal pain were enrolled. Patients were divided into 2 groups of surgical or medical intervention randomly. Medical group received 3 courses of 1.5 months 125 µg per puff, fluticason nasal spray (2 puffs Q 24 hours in each side), and oral Pseudoephedrin 30 mg Q 8 hours with 2 weeks intervals. Surgical group underwent turbinoplasty with functional endoscopic sinus surgery approach. Duration (per hour), frequency (per week) and severities of the headaches were measured by Visual Analog Scale (VAS) before treatment, and at 1.5, 3 and 6 months after institution of treatment by an examiner, who was unaware of the patients' treatment plan. **Results:** Before treatment, chronicity ($P = 0.980$), severity ($P = 0.742$), frequency ($P = 0.730$), and duration ($P = 0.603$) of the headaches were not significantly different. The severities of the headaches in surgical group were significantly lower at 1.5, 3 and 6 months ($P < 0.001$), also the frequencies and the durations of the headaches were significantly lower at 6 months after an institution of treatment compared to medical group ($P = 0.027$, $P = 0.008$, respectively). **Conclusion:** Turbinoplasty in chonca bullusa patients is an acceptable and a simple procedure for relieving pain in rhinogenic headaches, compared with medical treatment.

Key words: *Concha bullusa*, endoscopic intervention, frontal pain, medical treatment, periorbital pain, rhinoigenic headache, surgical treatment, turbinoplasty

INTRODUCTION

Headache is a common symptom, to the extent that 80% of the population suffers from the headache at least one time per year.[1] *Concha bullosa* (CB) is pneumatization of the middle turbinate and one of the most common anatomic variation of the sinonasal region. It is found in about 25% of the normal population. The main symptoms of this syndrome are headaches, an impaired nasal breathing and hyposmia. Headache is the most between a CB and other structures of the nasal cavity.[2] The incidence is increased in sinonasal patients, for example, an incidence of the co-existence of nasal septal deviation and CB has been reported in 44.6% of the patients.[3] In another study, an incidence of CB was found in 47 out of 100 Chinese with chronic sinusitis. From 100 Caucasian patients that had undergone a paranasal sinuses CT examination, 29% of them were affected by *concha bullosa*.[5] Unilateral or bilateral CB was found in 53% of the sinusitis patients.[6] In CT scans of the paranasal sinuses, CB was present in 34% of the patients.[7] Of 320 patients evaluated for sinus disease with coronal CT, 34% of them had CB on at least one side.[8] In computed tomographic scans from the patients with rhinosinusitis symptoms, the CB was present in 35% of the patients.[9] CB is more frequent in females between the presence of CB and an ethnicity.[10] Contact point headaches are one of the sub-groups of rhinogenic headaches. Dr. Commas (1960) was one of the pioneers, who described the rhinogenic headache.[11] It has been suggested that contact point can trigger headache in individuals with migraine.[12] In patients with primary

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headaches, the contact points may be refractory to the treatment. Contact point headaches and migraine without aura have similar symptoms (photophobia, nausea and vomiting, pulsating nature). Contact point headaches should be considered in these patients.[13] Ear, nose and throat (ENT) specialists play an important role in diagnosis of the headaches, such as mucosal contact point headache.[14] According to the location of pneumatization of middle concha, CB may be classified as lamellar, bulbous, and extensive types, but there is no significant relationship between the CB types and the sinus disease.[15] The most common type of the CB is middle turbinate pneumatization; however, superior and inferior turbinate pneumatizations have also been rarely reported.[16] In 74% of the patients, contact point headaches feel in periorbital region.[17]

The criterions for the diagnosis of a rhinogenic source of the headache or facial pain are as follows:

Headaches are not related to sinus problems such as polyps, sinusitis, tumors and foreign bodies, and the nasal cavity is considered as normal in routine examinations. Headaches are associated with an evidence of contact point by nasal endoscopy and/or CT imaging. During headache, an application of local anesthesia and local decongestants to this contact points will relieve the headache in 5 minutes.[17-19]

As reported in the classical work of Wolff (1948), the middle turbinate and the nasal septum is innervated by an anterior ethmoidal nerve, a branch of the ophthalmic division of the trigeminal nerve; stimulation of these regions causes pain in the medial canthus of the supraorbital region. Periorbital pain may be due to middle turbinate compression against the septum or the lateral wall of the nose, and it leads to the congestion of the nasal mucosa or pneumatization of the middle turbinate. The diagnosis of middle turbinate headache syndrome is made by exclusion and requires a high index of suspicion, anterior rhinoscopy, computerized tomography (CT), and confirmation by the Lidocaine test.[19]

Mucosal contact points between two mucosal surfaces result in stimulating of the C fibers that transmit an orthodromic impulse by triggering substance P (SP). Released SP induces vasodilation, hypersecretion, spasm of smooth muscles and extravasations of plasma from vessels. Antidromic release of SP is responsible for mucosal swelling during headache in the same side and the opposite side of the lesion.[20]

Modulation of pain transmission in the central nervous system (CNS) may also occur via an action of Enkefalin (EK). These physiologic sequences, in turn, are responsible for the subjective experience of pain in periorbital or frontal region. Rhinogenic headaches may be treated by surgical or medical interventions. Corticosteroid spray and decongestants are used in medical treatment.[21] Pneumatization (CB) or hypertrophy of the middle turbinate can result in its contact with the septum or the lateral nasal wall and may cause headaches in the periorbital region. The treatment is by relieving the contact point by surgical or medical options.[21]

Various methods of endoscopic surgery are used in treatment of these types of headaches for many years. Endoscopic turbinoplasty methods for CB included, removing the lateral wall of the CB, removing fronto-inferior part of CB, and turbinoplasty.[22-25]

An aim of this study was to evaluate an efficacy and the possible priority of surgical intervention in relieving the contact point headaches induced by CB, in contrast with medical treatment in two isolated, identical groups simultaneously.

MATERIALS AND METHODS

This randomized double blind clinical trial study was conducted between 2008 and 2009 in otolaryngology, eye and neurologic clinics of Mustafa Khomeini hospital Tehran, Iran.

We received the registration number (ACTRN12608000560392) after designing the study protocol.

Authors indicate that, the study design followed in accordance with the ethical standards of the Helsinki Declaration of 1975, as revised in 2008. The treatment process, including the advantages and disadvantages of each intervention were explained to the patients before the study. According to the sample size of the similar studies, 52 consecutive referral patients with periorbital or frontal headaches were considered for the surgical or medical interventions. Complete written informed consents were obtained from all the participants. The patients were assessed for eligibility and then were alternatively encoded and placed in each group considering the patients' acceptance.

The study protocol including the advantages and disadvantages of each intervention was approved by the Faculty of Medicine, Shahed University, and was confirmed by the scientific and ethics committee of Shahed University (Tehran, Iran).

Inclusion criteria

- Presence of chronic headache (>2 months), or pain or pressure feeling over the nasal bridge, glabella, or forehead as the main chief complaint without any apparent sinus disease including sinusitis, tumors, polyp or cyst in CT scanning of the nasal cavity and failure of standard medical therapy for headache.
- Normal ophthalmologic, neurologic and systemic examinations, despite the presence of the headaches.
- Existence of CB of middle turbinate in paranasal sinus coronal CT and visible contact points between the mucosal surfaces of middle concha and lateral wall in osteomeatal complex (OMC) region, or between medial wall and septum in diagnostic endoscopy of the nasal cavity.

- Relieving of the headache by an application of local anesthetic (2% Lidocaine) over the contact point.
- An absence of any other obvious cause of headaches after a complete evaluation by an ophthalmologist, neurologist, dentist, internist, or any other related specialist.

Exclusion criteria

- Previous sinonasal surgery.
- Active, acute or chronic sinonasal diseases, such as seasonal allergic exacerbations with mucosal swelling, infectious rhinosinusitis, or any prominent sinonasal problems:
- Severe nasal polyps mimicking contact points.
- Mucoceles protruding from sinuses into nasal cavity or any nasal and sinus tumors.
- General medical condition that precludes elective surgery (including pregnancy).
- Every contraindication for medications in medical group.

According to these criterions, 8 out of 52 patients, were excluded due to not meeting inclusion criteria (4 cases), declined to participate (2 cases), or did not complete the follow-up study (2 cases). Finally, out of 46 patients, 44 (19 male, and 25 female) cases were completed the study in 2 groups of 22 patients for each surgical or medical intervention. All the patients were completely examined by an otolaryngologist, ophthalmologist, neurologist, dentist, and an internist. Coronal computerized tomography (CT) of the nasal cavity (with 3 mm cuts) was performed for all patients. In surgical group (23 patients), turbinoplasty was performed. A sagital incision was made along an anterior surface of the middle turbinate, and then the contents within the middle turbinate including internal mucosa were removed by a straight forceps. It was important to remove all the mucosal contents from within the cells. The next step was to approximate the lateral and medial surfaces of middle concha. Therefore, in addition to splitting the contact points between two external sides of the mucosal surfaces, the middle concha becomes smaller. Turbinoplasty results in a significant reduction of large middle turbinate bullosa. This is a simple endoscopic procedure with short operative time.[24]

Medical group (23 patients) received 3 courses of 1.5 months treatment with Fluticason nasal spray 125 μg per puff (2 puffs Q 24 hours in each nasal cavity) and 30 mg Pseudoephedrin tablets Q 8 hours. In order to decrease the adverse effects of the medications, the treatments were discontinued for a period of 2 weeks, just before the 2nd and 3rd section of the treatment. 2 additional patients (1 patient in each group) were excluded due to irregular post-intervention visits and incomplete follow-up information. Finally, data analysis was performed for 22 patients in each group.

Characteristics of headaches in patients of both the groups were recorded by an assessor, blinded to the patients' treatment plans before and after interventions.

Duration (per hour) and frequency of the headaches (per week) were recorded. After preliminary training of all the patients, severities of headaches were measured in each group by Visual Analog Scale (VAS) before treatment, and at 1.5, 3 and 6 months after institution of treatment. Comparison of gender between the study groups was done with Chi-square test. Age and disease duration was compared with independent t-test. Changes in duration, frequency and severity of headaches during the follow-up were evaluated by Friedman test, separately in surgical and medical groups. Comparison of the headache factors between the surgical and medical groups was assessed with Mann-Whitney test. Analysis was done via SPSS 16 (SPSS Inc., Chicago, ILL), and $P < 0.05$ was considered as significant level.

RESULTS

There were no significant differences in gender ($P = 0.761$), age ($P = 0.0.976$) and chronicity ($P = 0.980$) between the 2 groups [Table 1]. Given the characteristics of headaches before an institution of treatment, severity, ($P = 0.742$), frequency ($P = 0.730$) and duration ($P = 0.603$) of the headaches were not significantly different between the 2 groups [Table 2]. Freedman test showed that the severity, frequency and duration of the headaches were significantly decreased in surgical group ($P < 0.001$ for all 3 items). Also, in medical groups, these 3 items were significantly decreased after medical treatment ($P = 0.001$, 0.001 and 0.003, respectively) [Table 2, columns].

After an institution of treatment, severities of headaches at 1.5, 3 and 6 months were significantly different between the surgical and medical groups as evaluated by Man-Whitney test ($P < 0.001$ for all 3 items). Moreover, this test revealed that the frequencies and durations of the headaches in surgical group were significantly different from the medical group only at 6 months from the beginning of the treatment

Table 1: Demographic characteristics of the patients in surgical and medical groups

	Surgical (*N* = 22)	Medical (*N* = 22)	*P*-value
Male/Female Ratio	9/13	10/12	0.761
Age (Years)	41.36 ± 13.76	41.27 ± 13.98	0.976
Chronicity (Year)	4.4 ± 1.8	4.06 ± 1.21	0.980

Gender ratio was reported as count and compared with Chi-squared test. Age and Chronicity (time from onset per years) were reported as mean ± Standard deviation and compared with independent t-test; *N* = Numbers

Table 2: Comparison of headaches between surgical and medical groups

	Treatment (Month)	Surgical (*N* = 22)	Medical (*N* = 22)	*P*- Value
Severity of headache* Median (range)	Before	7 (4-10)	6 (4-10)	0.742
	1.5	2 (0-8)	6 (3-8)	<0.001
	3	1 (0-5)	5 (2-8)	<0.001
	6	0 (0-5)	5.5 (0-9)	<0.001
	P-value	<0.001	<0.001	
Frequency of headache** Median (range)	Before	7 (4-10)	6 (4-10)	0.730
	1.5	1 (0-5)	2 (1-5)	0.325
	3	1 (0-2)	2 (1-5)	0.119
	6	0 (0-3)	2 (1-5)	0.027
	P-value	<0.001	<0.001	
Duration of headache*** (Mean ± SD)	Before	1.56 ± 0.91	1.18 ± 0.54	0.603
	1.5	0.93 ± 0.8	0.88 ± 0.36	0.591
	3	0.64 ± 0.7	0.81 ± 0.38	0.206
	6	0.37 ± 0.61	0.79 ± 0.41	0.008
	P-value	<0.001	0.003	

Before treatment, frequency, duration and severity of the headaches were not significantly different. The severities of the headaches in surgical group were significantly lower than medical group at 1.5, 3 and 6 months ($P < 0.001$), also, the frequencies and durations of the headaches were significantly lower at 6 months; *Frequency: Numbers of the headaches per week; **Duration: Duration of each single headache (hours); ***Severity measured by Visual analog scale; SD = Standard deviation

($P = 0.027$ and 0.008, respectively) [Table 2, rows]. Severity of the headaches was the first character that responded to the treatment followed by the frequency and the duration of the diseases. No significant side effects were encountered in each group.

DISCUSSION

This study showed that turbinoplasty in chonca bullusa patients is an acceptable and simple procedure for relieving of pain in rhinogenic headaches. In the study of Chow (1991_1992), 18 patients were enrolled, including: 12 cases with septal deviation and septal spur, 3 cases with sinus and 1 case with dehiscent infra-orbital wall. The patients were managed by surgical and medical interventions with a rate of 83% well-being [17]. The causes of the headaches varied more than the present study, and no comparison was made between the surgical and medical groups. In another retrospective review study by Parsons *et al*., conducted on on 15 children (6 to 15 years) and 19 adults (28 to 63 years) who were treated with surgical intervention, the causes of the headaches were large middle concha, large uncinate process, nasal spur, and double middle turbinate. The surgical intervention was done as directive endoscopic procedure on the lesion. The well-being symptoms were seen in 87% of the children and 84% of the adults. The follow-up time was 4.5 to 30 months. The severity of the pain was measured by questioner method.[26] In present study, the surgical procedure was done only on the middle CB, and the pain was measured by Visual Analog Scale (VAS) compared with control medical group. In the study of Nselmo (1997), 5 cases with middle turbinate headache syndrome, septal deviation and CB were presented. Of them, 4 were treated surgically by partial middle turbinectomy and septoplasty, with excellent results.[19] But, Har *el* and Slavit DH (1996) suggested that, the partial middle turbinectomy, especially with simultaneous uncinectomy and ethmoidectomy, increased the risk of an adhesion formation in middle meatus, while, turbinoplasty results in a significant reduction in the width of the middle turbinate without any damages to the mucosal surfaces.[24] Turbinoplasty technique was also used in the present study. In a similar study done by Ramadan HH (1999), 23 individuals with CB and hypertrophic concha and mucosal contact points were observed. Surgical intervention was undertaken for 15 cases, and the medical treatment was considered for the other 8 cases; the results were compared had surgery, reported marked relief of their headaches. [27]

The compared groups were not equal, and the patients had the middle CB and hyperthrophic concha; however, in the present study, the 2 groups were equal, and they just had the middle CB. Also, the methods of analysis and the details of the headaches characteristics are not identical. In the study of Giacomini P.G (2003), 34 patients with contact point headache that did not respond to the medical therapy, were analyzed by the Visual Analog Scale (VAS) after septoplasty, rhinoseptoplasty, and middle turbinate electro-cauterization. In 25% of the cases, the pain relapsed up to 1 year post-operatively, and the surgical results were superior to conservative nasal therapy treatment in the same group.[28] In the study of Mohebbi A *et al*. on 36 patients with chronic headaches who had not previously responded to conventional treatments, the intensity of the headaches, pre- and post-operatively, were compared by utilizing the VAS. The overall success rate approximated 83% after surgery. Surgery in specific cases of headaches with more positive evidence of contact point could be successful, particularly if medical therapy has failed.[29] Although in

present study, the headache severity has been analyzed by the VAS, the studied groups and the study design were different. Kunachak S (2002) introduced the middle turbinate lateralization as a safe and effective method in eliminating the symptoms of rhinologic cephalgia, induced by contact point between the middle turbinate and the nasal septum.[30] While in present study, de-bulking of the CB was the preferred surgical method. Also, Mariotti LJ *et al*. revealed that, endoscopic sinus surgery in rhinogenic headache was widely successful on their patients, and 28 (84.8%) of 33 patients had reported an improvement.[31] As an important difference with the others, in this study, the characteristics of the headaches were evaluated by an examiner, who was unaware of the patients' treatment plans. Some patients with refractory headaches and endo-nasal contact areas benefit from the surgery, thereby supporting an existence of a correlation between the two entities. Even though it is clear that surgery should be considered only if all other treatments have failed, a success rate of 65% over almost 10 years justifies an importance of this option. Pre-operative patient selection remains crucial and warrants further investigation.[32] Sinus headache (headache of rhinogenic origin) and migraine are frequently confused with each other. Considerable research and clinical study are needed to further understand the role of the nasal pathology and autonomic activation in migraine and rhinogenic headaches.[33]

CONCLUSION

In rhinogenic headache patients, simple surgical de-bulking of the CB in order to eliminate the contact points between the nasal mucosal surfaces is superior and cost-benefit method to medical management.

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Authors' contributions

Yarmohammadi ME carried out the frame work, co-ordination of the study and clinical examinations; Ghasemi H, participated in most of the experiments, patients evaluations and prepared the manuscript as the corresponding author; Pourfarzam S, provided assistance as an unaware examiner of the patients in the study; Jalali Nadoushan MR, provided assistance for the study design; Majd SA, participated in patients clinical examinations and referral of the patients. All authors have read and approved the content of the manuscript.

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